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INTER-AMERICAN COMPENDIUM OF REGISTERED VETERINARY PRODUCTS

Regulations and Authorities

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Héctor Campos, DVM and Pedro N. Acha, DVM.

Second Edition
May, 1989

INTER-AMERICAN COMPENDIUM - REGISTRATION OF VETERINARY PRODUCTS IN THE AMERICAS

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Inter-American Institute for Cooperation in Agriculture
(IICA)

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ABSTRACT

The regulations for the registration and control of veterinary products are presented for each of 29 countries, who are members of the Inter-American Institute for Cooperation in Agriculture and/or the Panamerican Health Organization (PAHO/WHO). Information about the registration process, the legal authority and the organizational structure of the agency responsible for registration in each of the countries is also presented.

ACKNOWLEDGEMENTS

The authors express their appreciation to several individuals and groups for their assistance in this duty. The contributions of the veterinary medical officers of the IICA and of the animal health services of the participating countries were paramount in obtaining the data. The financial support of the FDA and the USDA were essential for conducting the study. We specially acknowledge the contributions of Dr. Lester Crawford and Dr. Frank Mulhern whose constant support and interest helped maintain the original concepts expressed by the countries regarding the creation of a drug compendium and formed the stimulus for this study.

INTRODUCTION

Information sharing between most countries of the world in the areas of drug regulation, drug approval, animal feed additive registration, and drug and chemical residues of animal origin that represent a risk to the public health is not as well developed as information sharing in other scientific aspects of the veterinary medical sciences. The reasons are multiple and include political as well as commercial proprietary reasons. The primary reason, though, has been the lack of an organized system to collect and manage the data and to assist with the decision analyses that take place in this area.

Currently, each country in the world has its own system of registering drugs and feed additives. Moreover, conditions of use, dosages, and species in which use of a compound is approved vary from drug to drug among countries. Critical parameters such as withdrawal times, detection methodology and allowable drug combinations also vary among countries.

In 1984, the Inter-American Institute for Cooperation in Agriculture and the Virginia-Maryland Regional College of Veterinary Medicine decided to combine their efforts to develop an inter-American system to obtain and manage information on registered veterinary products. The Center for Veterinary Medicine of the United States Food and Drug Administration and the Food and Safety Inspection Service of the U.S. Department of Agriculture agreed to financially support the project.

The specific aim of the project is to develop and implement a system to collect, analyze and manage data concerning authorized veterinary products from member countries of IICA and the Pan-American Health Organization. The following objectives were set initially:

- Identification of the countries from which data will be collected and collection of data about their official structures and regulations for the authorization and control of veterinary products.
- Development of a system for receiving and sending back information to each country.
- Definition of the data elements and standardized nomenclature for the information base.
- Evaluation of currently available expert systems and other medical data base management systems for use in managing the data on registered veterinary products.

- Publication of the regulations and organizational structures of the countries participating in the project.
- Publication of a compendium of the registered veterinary products in each of the participating countries.
- Development of mechanisms to update the data base and exploration of means to make the project self-supporting in the future.
- Investigation of means to provide immediate access by electronic means to the data base for its analysis by member countries and organizations.

The purpose of the second edition of this publication is, besides presenting the official structures of the cooperating countries and the regulations they use in officially registering veterinary products, to present more detailed information about the registration procedures and the information required for the process in each country. Three more countries contributed to this publication: Bolivia, Cuba and Nicaragua. Each country supplied information on the following which is reported in a section for each country:

1. The legal bases for the registration procedures which includes the laws currently in effect, where they are published and how they can be obtained.
2. The authority responsible for registration of veterinary drugs and feed additives.
3. The number of people (human resources) involved in registering veterinary products in the country.
4. The official documents stating the requirements to register veterinary products and where they can be obtained.
5. The procedures for the registration of veterinary products; whether or not there are special application forms for this process, registration fees, etc.
6. Time for registration approval and duration of the licence.
7. The information required for registering veterinary products.
8. The presence or absence of defined criteria for accepting or refusing product registration.
9. Whether or not foreign studies are utilized in approval decisions.
10. Whether or not any products are exempt from registration.
11. Whether laws are in effect that require reporting of adverse reactions to a drug after it has been approved.
12. Whether or not relevant scientific data obtained by the manufacturer of the products after approval are required to be reported.
13. Whether or not surveillance of the utilization of registered products takes place and if so, by whom.
14. Wheter or not are requirements for importation of veterinary products.

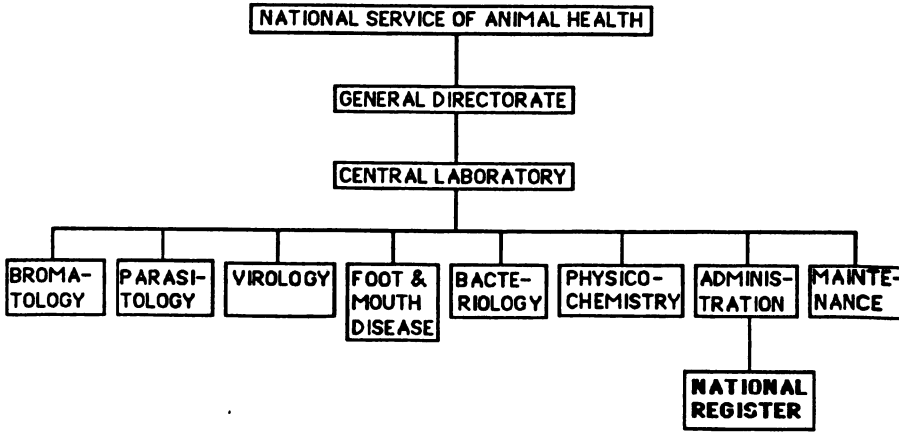
15. Whether or not there are national services for inspection of establishments manufacturing veterinary products and if so, who they are.
16. The official organizational structure of the organization responsible for registration of veterinary products.

The information of each country is presented on the following pages in alphabetic order.

ARGENTINA

Legal Basis	Decree Nº 583 of January 31, 1967 with the modifications established by Decree Nº 3899 of June 22, 1972. Law Nº 13,636 on surveillance of veterinary products, October 11, 1949. Laws and regulations have been published in the Official Newspaper *Diario Oficial.* Copies may be requested from the National Service of Animal Health.
Registration Authority	Laboratory Services, which is a component of the National Service of Animal Health.
Human Resources	Eighty.
Official Registration Document	Application for Product Registration ("Solicitud de Inscripción de Productos") of the Secretariat of Agriculture and Animal Husbandry, Ministry of Economy. It can be obtained from: Secretaría de Agricultura y Ganadería, Ministerio de Economía, Buenos Aires, República Argentina.
Registration Procedures	--
Time for Registration Approval	--
Information Required for Registration	Description of the product, trade name, name of the person presenting the application, address, manufacturer, place of manufacture, importing company, fractioning company, place of fractioning, distributor, cualitative and quantitative formula, clinical indications for its use, animal species, route and/or ways of administation, presentation form, dosage, contraindications, precautions, toxicity, storage, activity, controls.

Defined Criteria	Yes. Drugs must meet the requirements stated by the Decrees mentioned in Item 1.
Foreign Studies Accepted	Yes.
Exempt Products	No.
Adverse Reactions Reported	Yes, as defined in articles 13 and 14 of Decree Nº 583/67.
Post Registration Reporting	Yes, as defined in articles 13 and 14 of Decree Nº 583.67.
Post Registration Surveillance	The surveillance is done by the Laboratory Services and Sanitary Defense, both components of the National Service of Animal Health.
Importation Requirements	Yes.
Manufacturing Inspection	Yes. Laboratory Services (SELAB), National Register Area.



BARBADOS

Legal Basis	None. Food and Drug Regulations may be obtained from: Ministry of Health, Jemmonts Lane, Bridgetown, Barbados.
Registration Authority	None.
Human Resources	None.
Official Registration Document	--
Registration Procedures	--
Time for Registration Approval	--
Information Required for Registration	--
Defined Criteria	None for veterinary products registration.
Foreign Studies Accepted	Not applicable.
Exempt Products	All veterinary products are exempted from control of sale or use.
Adverse Reactions Reported	No.
Post Registration Reporting	Not applicable.
Post Registration Surveillance	No.

Importation Requirements	Only for veterinary biologicals and hormones.
Manufacturing Inspection	No.

BOLIVIA

Legal Basis	Regulations to Supervise Veterinary Products. Decree Nº 07783 of August 2, 1966. Copies of the regulations may be obtained from the General Directorate of Livestock of the Ministry of Rural Affairs and Animal Husbandry, La Paz, Bolivia.
Registration Authority	Technical Service of Livestock of the Ministry of Rural Affairs and Animal Husbandry.
Human Resources	--
Official Registration Document	Laboratories manufacturing veterinary products must be registered at the Techical Service of Livestock. In order to register, they must present an application in stamped paper to the Ministry of Rural Affairs and Animal Husbandry, with a certificate of inspection of the facilities and the name of the professional responsible for the manufacturing process. For the registration of the products, a written application in stamped paper for each product must be sunmitted to the Ministry of Rural Affairs and Animal Husbandry.
Registration Procedures	The application must be presented with samples of the product and instructions for its use. The receipt for the cost of the analysis must also be included. The product will be registered only after the results of the analysis performed by the official Laboratory have been known. The laboratory applying for the registration must present a certificate of inspection of its facilities performed by the Technical Service of Livestock.

Time for Registration Approval	60 days. If the analysis require more than 60 days, the applicant must ask for a temporary licence as long as the vital tests are satisfactory.
Information Required for Registration	Name and address of the Laboratory, name and address of the owner, name of the product, formula, samples, instructions for its use. The label must include the following: price and registration number given by the Ministry of Rural Affairs and Animal Husbandry.
Defined Criteria	A national or imported product is not approved for registration if its therapeutic qualities are not based on scientific facts or the chemical ingredients, dosage or indications for its use may be dangerous for the diagnosis, prevention or treatment of animal diseases.
Foreign Studies Accepted	Yes, but all the products must be qualitative and quantitatively analyzed in order to demonstrate the declared formula.
Exempt Products	Yes. The products imported by official entities for research purposes.
Adverse Reactions Reported	Yes, to the Technical Service of Livestock.
Post Registration Reporting	Yes. The Laboratory must notify to the Technical Service of Livestock.
Post Registration Surveillance	Yes.
Importation Requirements	Yes. The person interested must apply for authorization to the Technical Service of Livestock.
Manufacturing Inspection	Yes. Technical Service of Livestock.

Legal Basis

Decree Nº467 of 13.02.69 indicates the surveillance of products for veterinary use and manufacturing establishments.
Decree Nº64,499 of 14.05.69 approves the regulations for surveillance of products for veterinary use and manufacturing establishments.
Instructive Nº242 of 09.12.69, complements the regulations for surveillance of veterinary products and manufacturing establishments.
Relations of specific legislation about veterinary products.
Ministerial Instructive Nº 002 of 06.01.62, determines that the use of hormonal substances or similar natural or artificial products is only allowed for therapeutic use.
Ministerial Instructive Nº356 of 14.10.71 forbids the manufacturing and commercialization of chloride pesticides based on DDT and BHC, indicated against ectoparasites of domestic animals.
Instructive Nº88 of 03.12.75 approves the instructions for manufacturing of vaccines against anthrax.
Instructive Nº881 of 01.12.75 approves the instructions for the control of vaccines commercialization and antirabic sera for veterinary use.
Instructive Nº190 of 21.12.78 approves the instructions about regulations for production, control and use of hog cholera vaccine.
Instructive Nº24 of 17.01.80 approves the regulations for production, control and use of infectious bronchitis vaccine.
Instructive Nº47 of 02.08.76 approves the regulations for production, control and use of Newcastle disease vaccine.
Instructive Nº739 of 28.09.76 approves the regulations for production of foot and

mouth disease vaccine by private and official laboratories.
Instructive Nº24 of 04.04.78 states complementary regulations on production and control of foot and mouth disease vaccine.
The legislations are published in the Official Newspaper *Diario Oficial da União* and may be obtained from the Secretariat of Animal Sanitarian Defense (SDSA).

Registration Authority

Division of Veterinary Products (DIPROD) of the Secretariat of Animal Sanitarian Defense.
Laboratory support is done through the central and regional units of the National Laboratory of Animal Reference (LANARA). Formulas and feed additives are registered by a unit of the National Secretariat of Animal Husbandry Defense, the Division of Surveillance of Foods (DIFISA) that belongs to the Secretariat of Animal Husbandry Surveillance.

Human Resources

The actual number devoted to product registration is not measurable because persons involved also perform other activities.

Official Registration Document

"Regulamento de Fiscalizaçao de Produtos de Uso Veterinario e dos Estabelecimentos que os Fabriquem". The regulations may be obtained from: Divisão de Produtos Veterinários (DIPROD), Secretaria de Defesa Sanitária Animal (SDSA), Secretaria Nacional de Defesa Agropecuária (SNAD), Ministério de Agricultura, Brasilia, Brasil.

Registration Procedures

The application must be presented to the Division of Veterinary Products (DIPROD), Ministry of Agriculture.
The manufacturer outside the country that wishes to introduce a product to Brazil must have a representative registered at the ETEDA (Equipe Técnica de Defesa Sanitária Animal). The application for registration must be presented to the Director of ETEDA by the laboratory

manufacturing the product or its legal representative.
The establishments importing, manufacturing or fractioning products must pay taxes according to Art.66, Chapter VII of Decree Nº64.499 of the Regulations.

Time for Registration Approval

Approximately 45 days and the licence is valid for 10 years for the products manufactured in the country and 3 years for imported products.

Information Required for Registration

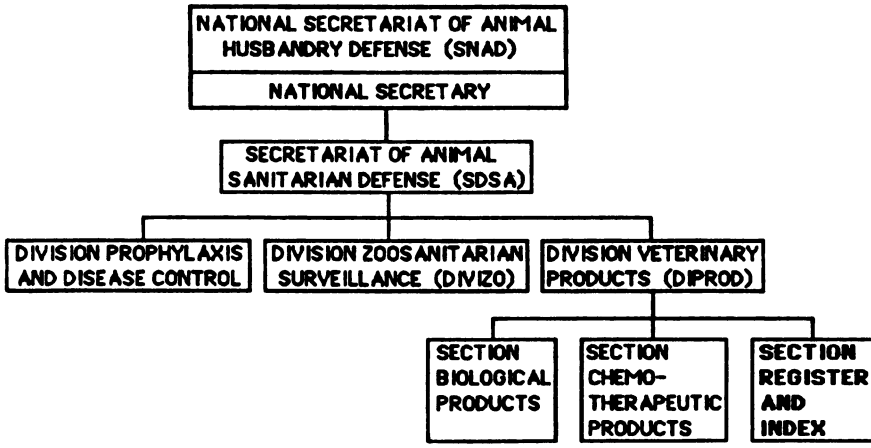
Name of the product, name and registration number of the responsible person, name of the manufacturing laboratory, name of the formula's owner, place of manufacture (name and address), licence number of the manufacturing establishment, legal basis for the application for registration or renewal, form of presentation of the product, composition, route of administration, indications, contraindications, expiration date, storage conditions, way of action, maximum and minimum dosages, complete formula of the ingredients, manufacturing techniques, codes used by the manufacturer to indetify the product.
The documents accompanying the application must be legalized by the authorities and translated to portuguese if necessary.
The manufacturer outside the country must present the following information to ETEDA: name and address of its representative in Brazil, name and address of the establishment, description of the product, legal basis for applying for registration.

Defined Criteria

The registration of veterinary products depends on analysis presented by the manufacturer. If the product is of interest for national programs (ex:vaccines) there is specific legislation for their production, quality control and use. In these cases, all production, batch by batch is tested prior to its location in the market. Sterility, safety and efficacy tests are done by official laboratories.

Foreign Studies Accepted	The studies performed by the manufacturer are considered in terms of analysis that must be done.
Exempt Products	No.
Adverse Reactions Reported	Yes. The Official Service performs systematic surveillance studies about the reactions, and it is allowed to apply appropiate actions.
Post Registration Reporting	The legislation does not enforce the manufacturer to present information, however this is usually given, requesting changes of the original registration.
Post Registration Surveillance	Yes. The basic legislation Nº64.499/69, active since December 1969, establishes the mechanism of surveillance during manufacturing, quality control process and product commercialization.
Importation Requirements	Yes. They are established in the legislation and require an officer from Brazil, and previous register of the corresponding products that are going to be imported.
Manufacturing Inspection	See "Post Registration Surveillance". Inspection is required by law for the purpose of registration and is valid for one year. The Service can perform additional inspections whenever they desire.

BRAZIL


NATIONAL SECRETARIAT OF ANIMAL HUSBANDRY DEFENSE (SNAD)
NATIONAL SECRETARY
SECRETARIAT OF ANIMAL SANITARIAN DEFENSE (SDSA)
DIVISION PROPHYLAXIS AND DISEASE CONTROL
DIVISION ZOOSANITARIAN SURVEILLANCE (DIVIZO)
DIVISION VETERINARY PRODUCTS (DIPROD)
SECTION BIOLOGICAL PRODUCTS
SECTION CHEMO-THERAPEUTIC PRODUCTS
SECTION REGISTER AND INDEX

Legal Basis

Drugs:Food and Drug Act and Regulations.
Biologics: Animal Disease and Protection Act. Laws and regulations published in Otawa and can be obtained from: Supply and Services Canada, Publishing Centre, Hull, Quebec, K1A OS9, Canada. Cost: $46-70 (canadian).
Food and Drug Act and Regulations Cat. #H-41-1-1984.
Animal Disease and Protection Act Cat. #RE-344.

Registration Authority

Drugs: Bureau of Veterinary Drugs, Health Protection Branch (HPB), Health and Welfare Canada.
Biologics: Veterinary Biologics Section, Animal Health Division, Food Production and Inspection Branch (FPIB), Agriculture Canada.

Human Resources

	Drugs	Biologics
Veterinarians:	19	4
Pharmacists:	1	-
Chemists:	1	-
Other:	9	3

Official Registration Document

New drugs: Form HPB 3011.
Not new drugs:Drug Identification Number Application Form.

Registration Procedures

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Time for Registration Approval

Two weeks.

Information Required for Registration

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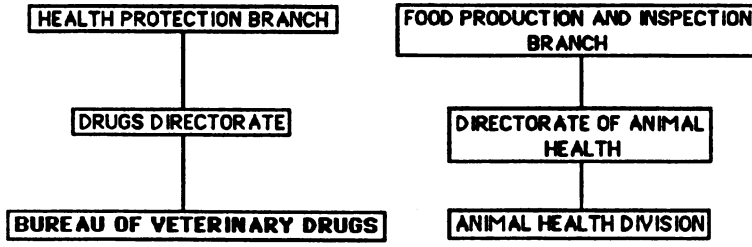
Defined Criteria

The data generated in initial studies by drug manufacturers must provide satisfactory evidence that the drug meets the required

	standards when used as recommended on the label with respect to the following: Drugs: toxicity, residues, safety in the intended species, efficacy. Biologics:manufacturing and quality control re-formulation, stability, purity, sterility.
Foreign Studies Accepted	Yes, provided the standards applied to all aspects of the study are similar to national standards. Drugs to be used in food producing animals may require confimatory studies conducted under Canadian conditions.
Exempt Products	No.
Adverse Reactions Reported	Yes. Reporting required within 15 working days of incident. Veterinary practitioners are encouraged to report to the Bureau of Veterinary Drugs. The Bureau publishes twice yearly accumulated information in the Canadian Veterinary Journal.
Post Registration Reporting	Yes.
Post Registration Surveillance	Yes.
Importation Requirements	Yes.
Manufacturing Inspection	Yes. Drugs: inspection under Field Operations Directorate, Health Protection Branch, National Health and Welfare. Biologics: Veterinary Biologics Section, Animal Health Division, Food Production and Inspection Branch,Agriculture Canada.

CANADA


HEALTH PROTECTION BRANCH
DRUGS DIRECTORATE
BUREAU OF VETERINARY DRUGS
FOOD PRODUCTION AND INSPECTION BRANCH
DIRECTORATE OF ANIMAL HEALTH
ANIMAL HEALTH DIVISION

CHILE

Legal Basis

Ministry of Health: Decree Nº 466, 1984; approval of regulations for pharmacies, drugstores, pharmaceutical stores, drug cabinets and authorized warehouses.

Decree Nº 435, November 30, 1981; approval of regulations for the National Control System of Pharmaceutical Products, Foods for Medical Use and Cosmetics.

Decree Nº 725, January 31, 1968; Sanitarian Code.

Ministry of Agriculture: Decree Nº 307, October 25, 1979; approval of regulations for animal foods.

Decree Nº 302, October 20, 1980; modifications of Decree Nº307; regulations for animal foods.

Resolution Nº 557, March 14, 1980; establishes the list and warranty for the food ingredients to be used in the manufacture of foods or suplements for animals.

Resolution Nº 1763, August 10, 1981; establishes sanitary requirements for industries manufacturing food and/or additives for animals.

Resolution Nº 1764, August 10, 1981; establishes the list and warranty of the additives used in the manufacture of food and supplements for animals.

Resolution Nº 1765, August 10, 1981; establishes the requirements for the production of animal food.

Laws have been published in the Official Newspaper of Chile *Diario Oficial*. Printed in *La Nación*. Agustinas 1269, Casilla 81-D, Santiago, Chile.

Registration Authority

Drugs and biologicals: The Public Health Institute (Ministry of Health).

Feed additives for animals: The Agriculture and Livestock Service (Ministry of Agriculture).

Human Resources

Agriculture and Livestock Service is in charge of the control at both central and regional level.
Central:
a) Supplies Unit, Division of Animal Husbandry Protection - 2 veterinarians.
b) Laboratory of Quality Control of Biological Products - 12 veterinarians; 2 pharmacists.
Regional:
Region I to XII and Metropolitan Region - 58 veterinarians in charge of the control of the handling of pharmaceutical veterinary products in the field and also in the customs at the border; they inspect the import of pharmaceutical products for animal use.

Public Health Institute: 27 professionals distributed as follows:
a) Subdepartment of Authorization and Registration - 3 pharmacists.
b) Subdepartment of Analytical Chemistry - 18 pharmacists.
c) Inspectors of Pharmaceutical Industries - 3 pharmacists.

Official Registration Document

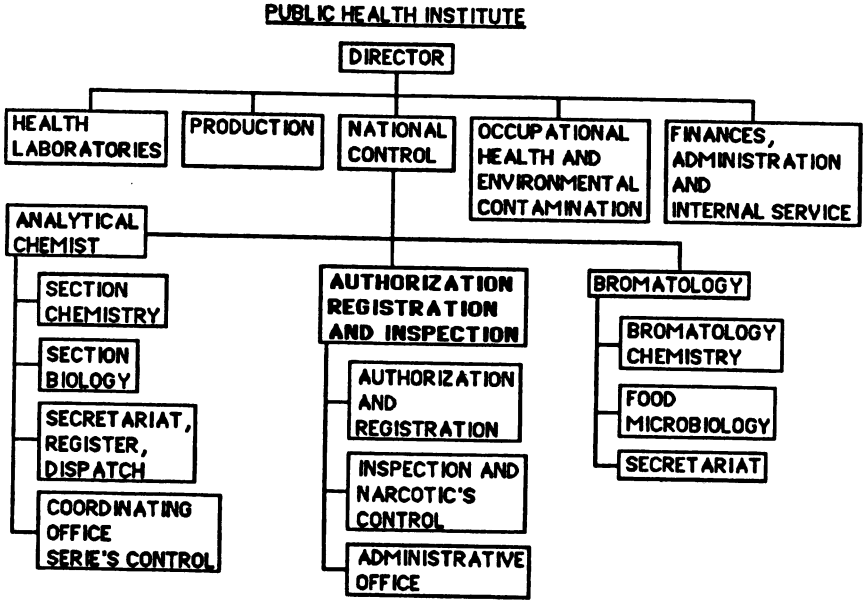
"Solicitud para Autorización y Registro de Productos Farmacéuticos de Uso Veterinario" (Application for Authorization and Registration of Pharmacological Products for Veterinary Use), of the Public Health Institute, Dept. of National Control, Ministry of Health. There is no registration fee and the application may be obtained from:
Instituto de Salud Pública.
Avda. Marathon 1000. Santiago, Chile.

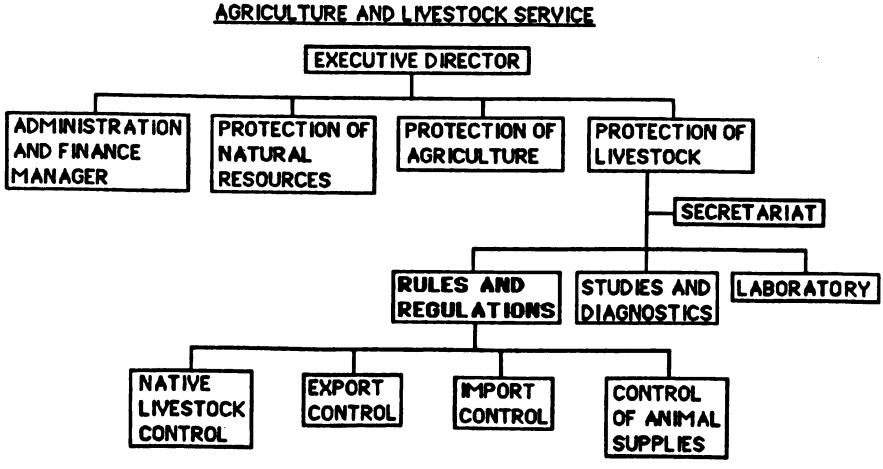
Registration Procedures

The application must be presented to the Dept. of National Control of the Institute of Public Health and must be suscribed for the applicant or his/her legal representative and the professional in charge of this matter.
The Agriculture and Livestock Service of the Ministry of Agriculture, by its Division

	of Animal Husbandry Protection mut present, if required by the Ministry of Health, a technical report for products to be used in animals. In the case of biological products, they must be submitted to efficacy, efficiency, purity, safety tests and physico-chemical tests.
Time for Registration Approval	Approximately 180 days.
Information Required for Registration	a) Qualitative and quantitative formulas expressed in the metric system or conventional international units and suscribed by the responsible person. The following must be considered: - all the ingredients must be expressed by their generic and/or chemical names and in spanish. - efficacy period, when applicable, supported by scientific relevant information. b) Clinical and pharmacological information in spanish from reliable sources and supported by the professional suscribing the application. c) Label proposals in spanish. d) Enough samples of the product. e) Standards of the active ingredients . f) Analytical methodology in spanish, suscribed by the professional presenting the application. g) Scientific information related to: manufacture and quality control, pharmacological studies performed in animals, pharmacokinetic studies, toxicological studies in animals and clinical studies. h) The following legal documents: trade name certificate, free sale certificate from the country of origin, authorization of the exporting company, manufacturing agreement, foreign manufacturing agreement.
Defined Criteria	Yes. If drugs do not meet the actual dispositions contained in the acting laws.

Foreign Studies Accepted	They are used as reference before making the decision.
Exempt Products	No. In the regulations there are causes for liberation of registration in qualified cases that might be the following: according to Art.15, Decree 435 of Ministry of Health, "The Director of the Institute may authorize by resolution, the import, manufacture and provisional use of a product, without previous registration, when it is required for urgent uses, for scientific research, clinical assays or other well qualified cases".
Adverse Reactions Reported	Yes. According to paragraph 2, Section 48, Decree 435 of the Ministry of Health that says: "Warning for a safe and effective use, noting the contraindications, interactions and/or adverse reactions, all done according to the instruction of the Institute when the registration is approved".
Post Registration Reporting	Yes. In (K) of Section 46, Decree 435, it says: "Any other instruction that might be considered pertinent by the Institute when the registration is approved or that may be determined after the registration was accepted".
Post Registration Surveillance	Yes.
Importation Requirements	Yes.
Manufacturing Inspection	Yes. Included in Item 3.


PUBLIC HEALTH INSTITUTE
DIRECTOR
HEALTH LABORATORIES
PRODUCTION
NATIONAL CONTROL
OCCUPATIONAL HEALTH AND ENVIRONMENTAL CONTAMINATION
FINANCES, ADMINISTRATION AND INTERNAL SERVICE
ANALYTICAL CHEMIST
SECTION CHEMISTRY
SECTION BIOLOGY
SECRETARIAT, REGISTER, DISPATCH
COORDINATING OFFICE SERIE'S CONTROL
AUTHORIZATION REGISTRATION AND INSPECTION
AUTHORIZATION AND REGISTRATION
INSPECTION AND NARCOTIC'S CONTROL
ADMINISTRATIVE OFFICE
BROMATOLOGY
BROMATOLOGY CHEMISTRY
FOOD MICROBIOLOGY
SECRETARIAT


AGRICULTURE AND LIVESTOCK SERVICE
EXECUTIVE DIRECTOR
ADMINISTRATION AND FINANCE MANAGER
PROTECTION OF NATURAL RESOURCES
PROTECTION OF AGRICULTURE
PROTECTION OF LIVESTOCK
SECRETARIAT
RULES AND REGULATIONS
STUDIES AND DIAGNOSTICS
LABORATORY
NATIVE LIVESTOCK CONTROL
EXPORT CONTROL
IMPORT CONTROL
CONTROL OF ANIMAL SUPPLIES

COLOMBIA

Legal Basis

Decree Nº 843 of 1969 which dictates dispositions on industry and commerce control of fertilizers, soil conditioners, animal food, plaguecides for agricultural use, defoliants, physiological plant regulators, drugs and biological products for veterinary use.

Resolution 23,333 of 1984 of the Colombian Animal Husbandry Institute (ICA), regulates the industry and commerce of seminal material.

Resolution Nº 1152 of 1981 ICA, by which Decree 843 is regulated in the matter of industry and commerce of animal food.

Resolution Nº 1764 ICA, which regulates Resolution 0261 of Ministry of Agriculture, related to the quality of poultry chosen for breeding, commercials of first generation and fertile eggs for hatching.

Resolution Nº 710 of 1981 ICA, which regulates Decree Nº 843 of 1969 in relation to industry and commerce of drugs and biological products for veterinary use.

Resolution Nº1326 of 1981 ICA, which gives dispositions for utilization and commercialization of antimicrobial products for veterinary use.

Resolution Nº2218 of 1980 which gives dispositions about labeling of drugs for veterinary use.

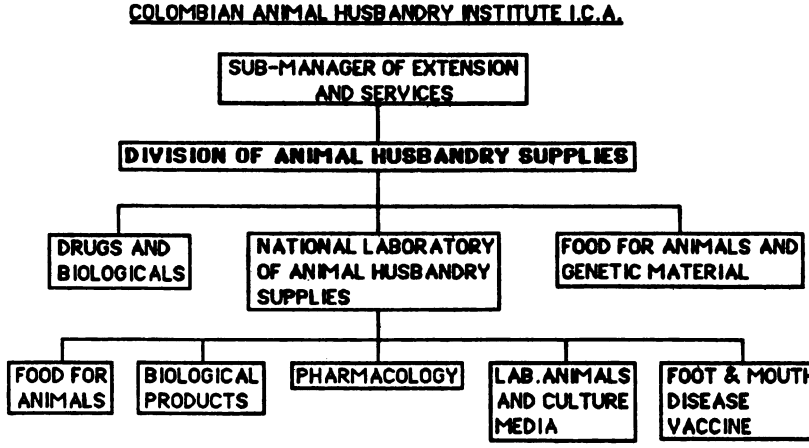
Resolution Nº 1966/84 of ICA, which regulates the use of antimicrobial substances as promoters of growth or improvers of alimentary efficiency.

Laws may be obtained in the Colombian Animal Husbandry Institute ICA, Bogota either at its Secretariat or through the Division of Aninal Husbandry Supplies, under the Sub-Manager of Extension and Services of ICA.

Registration Authority	The Colombian Animal Husbandry Institute (ICA) is in charge of veterinary products registration through the Sub-Manager of Extension and Services in the Division of Animal Husbandry Supplies. There are sections for Drugs and Biologicals, Foods and Genetic Materials, and the National Laboratory of Animal Husbandry Supplies.
Human Resources	Division of Animal Husbandry Supplies - 1 Section Drugs and Biologicals - 1 Section Food and Genetic Materials - 2 National Laboratory of Animal Husbandry Supplies - 1
Official Registration Document	Resolution Nº 710 of April 6, 1981 regulates Decree Nº 843 of 1969 in relation to industry and commerce of drugs and biological products for veterinary use. The document may be obtained from the Colombian Animal Husbandry Institute (ICA), Bogotá, Colombia.
Registration Procedures	The manufacturer must present an application in stamped paper to the Colombian Animal Husbandry Institute through the respective regional office. If the requirements stated in Resolution 710 are met, ICA will grant the registration licence as a producer and/or importer through a Resolution.
Time for Registration Approval	If the requirements are not met,the applicant has 3 months from the day he was notified, to do the necessary errands before ICA and met the missing requisites. If no modifications are made within this period, the application expires and a new one must be presented with the established requirements.
Information Required for Registration	--
Defined Criteria	The main criteria for refusal has to do with technical or scientific aspects. Products are

	refused when studies demonstrate they are dangerous for human and/or animal health or because, they have not been shown to be efficacious.
Foreign Studies Accepted	Scientific literature is required, which justifies the use of the product at the concentration, dose and for the diseases and species indicated. Pharmaceutical and toxicological information as well as the presence of residues in animal tissues is also required. Therapeutic, nutritional and pharmacological parameters established by widely recognized international organizations are considered as well as parameters determined by ICA. The performing of an efficiency test in the country on the active ingredient of the product and its indications is a requisite for registration.
Exempt Products	No.
Adverse Reactions Reported	No, but when they happen regularly, ICA must be notified. In the technical studies of the products, when they are presented to ICA for their registration, the precautions and contraindications must appear on the label of the product.
Post Registration Reporting	Yes.
Post Registration Surveillance	Yes.
Importation Requirements	The Resolution Nº 710/81 of ICA establishes the points and requirements that must be accomplished by the importers, as well as the veterinary products to be imported or the raw materials necessary for the production of drugs.
Manufacturing Inspection	ICA has professionals in different regions that perform inspection of establishments manufacturing veterinary products.

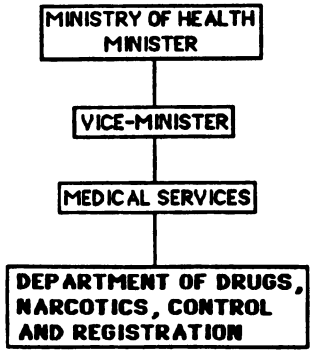
COLOMBIA


COLOMBIAN ANIMAL HUSBANDRY INSTITUTE I.C.A.
SUB-MANAGER OF EXTENSION AND SERVICES
DIVISION OF ANIMAL HUSBANDRY SUPPLIES
DRUGS AND BIOLOGICALS
NATIONAL LABORATORY OF ANIMAL HUSBANDRY SUPPLIES
FOOD FOR ANIMALS AND GENETIC MATERIAL
FOOD FOR ANIMALS
BIOLOGICAL PRODUCTS
PHARMACOLOGY
LAB. ANIMALS AND CULTURE MEDIA
FOOT & MOUTH DISEASE VACCINE

COSTA RICA

Legal Basis	Regulations on Registration and Propaganda of Drugs and Cosmetics, Decree Nº 6365 of the Ministry of Health. Published in *La Gaceta* Nº 187, point Nº 172, September 23, 1976.
Registration Authority	Department of Drugs, Narcotics, Controls and Registration. Ministry of Health.
Human Resources	25 professionals distributed as follows: Pharmacists: 15 Chemists: 4 Microbiologists: 5 Attorney at Law: 1
Official Registration Document	The registration procedures are described in the Regulations on Registration and Propaganda of Drugs and Cosmetics ("Reglamento de Inscripciones y Propaganda de Medicamentos y Cosméticos"), Decree Nº 6365 of Ministry of Health. This document may be obtained from: Departamento de Drogas, Narcóticos, Controles y Registros, Ministerio de Salud, San José, Costa Rica.
Registration Procedures	Manufacturing companies must be registered at the Office of Drug Registration. Then, the company may apply for registration of the product before the same office, presenting two samples of the product in the form and conditions that is going to be sold to the public. Besides, two receipts must be presented: one given by the School of Pharmacists against registration fee, and another for the cost of laboratory analysis. If the product is sold in different forms or concentrations, a separate application for each one is required.

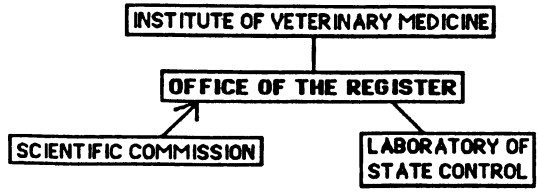
Time for Registration Approval	30 working days from the day the application was presented. In special cases, if complementary analysis are required, the Concil may extend the date.
Information Required for Registration	Described in "Regulations on Registration and Propaganda of Drugs and Cosmetics".
Defined Criteria	It depends on the product to be registered. For example, refusal occurs when attempts are made to register a biological product for controlling a disease that does not exist in the country.
Foreign Studies Accepted	Yes.
Exempt Products	No.
Adverse Reactions Reported	Yes.
Post Registration Reporting	Yes.
Post Registration Surveillance	Yes.
Importation Requirements	Yes. Described in the Regulations.
Manufacturing Inspection	Authorization is given to operate for two years. The country has a Control Service for Pharmacies at a national level.



CUBA

Legal Basis	Resolutions Nº 222 and 223, 1984 of the Ministry of Agriculture and Regulations for the manufacture, control, distribution, export and import of veterinary drugs. Resolution 44/85 of the Institute of Veterinary Medicine. Resolutions 222 and 223 of 1984 were published in the *Gaceta Oficial* of the Republic of Cuba, Nº 18 of year LXXXII, October 20, 1984, pages 91-94. The laws and regulations can be obtained from the Institute of Veterinary Medicine.
Registration Authority	Office of the Registration of Veterinary Drugs of the Institute of Veterinary Medicine. This office works in consultation with the Register Scientific Commission and the Laboratory of State Control.
Human Resources	Veterinarians: 10 Pharmacists: 2 Chemists: 2 Technicians: 45
Official Registration Document	There is an application form to register veterinary products.
Registration Procedures	The application must be presented with samples of the products. A fee for laboratory analysis must be paid.
Time for Registration Approval	180 days at the most.
Information Required for Registration	The registration form contains all the registration requirements.
Defined Criteria	Yes. Refusal of registration occurs when drugs do not meet the legal requirements or the results of their analysis are not satisfactory or denots undesirable effects. The Register Scientific Commission will

	ultimately decide if a product is registered or not.
Foreign Studies Accepted	Yes, but some necessary analysis must be performed by the Laboratory of State Control.
Exempt Products	No.All veterinary drugs must be registered.
Adverse Reactions Reported	Yes; their notification is mandatory.
Post Registration Reporting	Yes. It is mandatory for the manufacturer and it is stated in the Regulations.
Post Registration Surveillance	Yes.
Importation Requirements	Yes.
Manufacturing Inspection	Yes. It is performed by inspectors of the Laboratory of State Control.



Legal Basis	None.
Registration	Not applicable.
Human Resources	Not applicable.
Official Registration Document	Not applicable.
Registration Procedures	Not applicable.
Time for Registration Approval	Not applicable.
Information Required for Registration	Not applicable.
Defined Criteria	Not applicable.
Foreign Studies Accepted	Not applicable.
Exempt Products	Not applicable.
Adverse Reactions Reported	Not applicable.
Post Registration Reporting	Not applicable.
Post Registration Surveillance	Not applicable.
Importation Requirements	No.
Manufacturing Inspection	Not applicable.

DOMINICAN REPUBLIC

Legal Basis

Resolution Nº 31/85 of April 24, 1985: "Regulations for Registration and Certification of Medicines, Patents, Pharmaceutical Specialties, Pesticides, Disinfectants, Cosmetics, and similars, and the Establishments dedicated to Commercial and Industrial Activities of these Products, with the purpose of Sanitary Inspection". Published on May 15, 1985 in the newspaper *El Nuevo Diario* .

Law Nº 259, December 31, 1971 about production and commercial quality of animal food.

Decree Nº 2162, April 14, 1972 requests the registration of formulations for animal food to the General Directorate of Livestock.

Decree Nº 625, February 1, 1979 modifies Articles 12,14,15,16 and 17 of the Regulation 2162 dated April 14, 1972.

Law Nº 8, September 8, 1965 creates the State Secretariat of Agriculture and establishes its own Organic Regulation which is contained in Decree 1142 dated April 28, 1966.

Law Nº 4030, January 15, 1955 proclaims of public interest the Sanitary Defense of livestock. In paragraph I of Article 27 it rules on importation of veterinary products.

Laws and regulations are published in the Official Bulletins, Nº 8446, 8982 and 7793.

Registration Authority

Section Registration of Veterinary Products of the Division of Livestock Transit, Department of Animal Health, Livestock General Directorate, State Secretariat of Agriculture.

Human Resources

Two employees in the Section Registration of Veterinary Products. Inspectors in ports

and airports do control of any product that does not meet the legal requirements. Three employees in the section of Food and Feed Control (2 chemists and 1 technician).

Official Registration Document

The registration procedures are described in the Regulation for Registration and Certification of Medicines, Patents, Pharmaceutical Specialties, Pesticides, Disinfectants, Cosmetics, and similars, and the Establishments dedicated to Commercial and Industrial Activities of these products with the purpose of Sanitary Inspection.

Registration Procedures

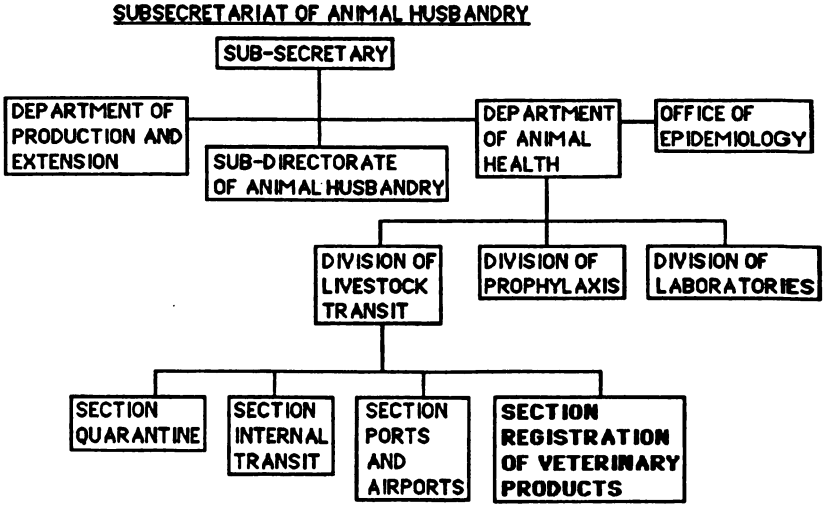
The manufacturing establishment must be registered in the State Secretariat of Agriculture, Livestock General Directorate. In order to register a veterinary product, three copies of the application must be presented to the Section Registration of Veterinary Products, Livestock General Directorate, State Secretariat of Agriculture. One copy goes to the person applying for the registration; other to the Official Laboratory chosen by the State Secretariat of Agriculture, and the third copy goes to the Technical Committee of the Department of Animal Health for its review and study. The application must be presented with: two samples of each product in the form that is going to be sold; two samples of each brochure that is going to be used for propaganda. If the product comes from another country: a legalized certificate stating that the product is sold with the same name and formula in the original country without restriction. For these products, the foreign manufacturer must also legally authorize a representative in Dominican Republic.
The cost of the registration is: RD$25.00 pesos for the national, and RD$50.00 for the foreign products.

Time for Registration Approval

The applications are reviewed as they come and the samples are sent to the chosen laboratories for the analysis. The laboratories have 45 days to emit the

	results, but the time may be extended if special tests are required. The extension must be notified to the applicant. The registration is not transferable and must be renewed every 5 years, paying half of the regular fee.
Information Required for Registration	Name and address of the person presenting the application; name of the product; name of the manufacturer; location of the manufacturing company; laboratory or establishment where the product is manufactured; name and address of the importer or its representative; qualitative and quantitative formulas; preparation techniques in the case of biological products, sera, vaccines and similars; dosage; uses of the product. If the product has unknown ingredients, original papers translated to Spanish and pharmacodynamic properties of the ingredients and its uses must also be presented.
Defined Criteria	Yes. The criteria for refusal are: a) when the products do not agree with the requirements established in the regulations; b) when the products do not satisfy the field and laboratory tests, according to their characteristics; c) when, according to well known scientific research, it is proved that certain products may cause uncontrolled sanitary problems to the national livestock; d) biological products to be used against diseases not present in the country.
Foreign Studies Accepted	Yes, but a free selling certificate from the country of origin is requested, and must be legalized by the consular authorities of the country and the official organizations of the originating country.
Exempt Poducts	No.
Adverse Reactions Reported	Yes.

Post Registration Reporting	Yes.
Post Registration Surveillance	Yes. Article 12 Law Nº 8, Point J.
Importation Requirements	Yes. The State Secretariat of Agriculture will authorize the import only to registered companies.
Manufacturing Inspection	No.



ECUADOR

Legal Basis

Animal Sanitation Law. Official Registration Nº 409, March 31, 1981.

Special Regulation for Production and Commercialization of Chemical, Biological and Similar Products for Veterinary Use. Official registration Nº 618, November 14, 1983.

They can be obtained from: National Program of Animal Sanitation, Ministry of Agriculture and Livestock, or at the Offices of the State Official Registration, Legislative Palace, Low Floor, Quito, Ecuador.

Registration Authority

Department of Sanitary Control of the National Program of Animal Sanitation, Ministry of Agriculture and Livestock.

Human Resources

Veterinarians: 2
Assistant: 1
Secretary: 1

Official Registration Document

Special Regulation for Production and Commercialization of Chemical, Biological and Similar Products for Veterinary Use ("Reglamento Especial para la Producción y Comercialización de Productos Químico-Biológicos y demás de Uso Veterinario"). It may be obtained from: Oficinas de Registro del Estado. Palacio Legislativo, Planta Baja, Quito, Ecuador.

Registration Procedures

An application for registration must be presented with samples of the product in its final form. A fee for laboratory analysis must also be paid. The registration fee for national products is $1.500 pesos, and for imported products: $2.500 pesos.

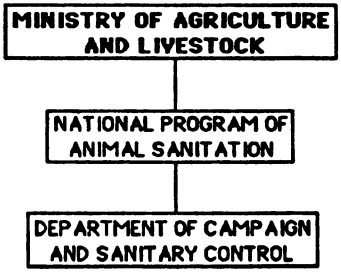
In the case of imported products, a free sale certificate extended by the originating country and legalized by the ecuatorian Consulate must be enclosed.

Time for Registration Approval	15 days. If the registration is refused, the National Program of Animal Sanitation will explain the reasons for this decision in a writen form within 10 days. The registration licence is valid for 7 years from the date in which the certificate is extended.
Information Required for Registration	The application must be presented with: name of the manufacturer or importer, trade name of the product, chemical formula, commercial literature if available, protocol of pharmacological information and possible tests to which the product may be subjected, method of analysis, qualitative and quantitative formulas, certificate extended by the Register stating the legal existence of the Company, certificate extended by the Superintendent of Companies stating that the company is up to date in its obligations with this institution, copy of the certificate in which the legal representative is nominated. If the applicant is a natural person: copy of the Tax Control Card and commercial licence.
Defined Criteria	Yes. Registration of biologicals is approved only for those that protect against prevalent diseases in the country, and it is refused when the pharmaceutical products do not meet the technical requirements for its use, according to the Analysis Protocol.
Foreign Studies Accepted	Yes.After examining the Protocol, methods of analysis, characteristics and use of the product.
Exempt Products	No.Registration is required for all imported and domestic veterinary products.
Adverse Reactions Reported	No.
Post Registration Reporting	No.
Post Registration Surveillance	Yes. Provincial and local veterinarians of the National Program of Animal Sanitation enforce the proper use of registered

products.

Importation Requirements — Yes. Laws and regulations state the requirements for importation.

Manufacturing Inspection — Yes. The Izquieta Perez Institute, from the Ministry of Public Health.



EL SALVADOR

Legal Basis	Regulation for Law on Control of Pesticides, Fertilizers, and Products for Animal and Agriculture Use; Decree Nº 28 of the Executive Power. October, 1979.Published in the Official Newspaper Nº 101,Chapter 267, May 30, 1980. Law on Control of Pesticides, Fertilizers and Products for Animal and Agriculture Use. May 4,1973. Published in the Official Newspaper Nº 85, Chapter 239, May 10, 1973. Law on animal husbandry sanitation. Published in the Official Newspaper Nº 142, Chapter 192, August 9, 1961.
Registration Authority	Directorate of Animal Husbandry Defense of the Ministry of Agriculture and Livestock.
Human Resources	Four professionals.
Official Registration Document	Regulation for Law on Control of Pesticides, Fertilizers and Products for Animal and Agriculture Use ("Reglamento para la Aplicación de la Ley sobre Control de Pesticidas, Fertilizantes y Productos para Uso Agropecuario"). Decree Nº 28 of the Executive Power. October, 1979.
Registration Procedures	A form called "Register Control" must be filled out and presented with seven samples and seven labels of the product. The following documents must also be included: certificate of analysis, certificate of origin, free sale certificate, technical and commercial literature on the product, methods of analysis, information about different packaging forms.
Time for Registration Approval	--

Information Required for Registration	Name of the product, name of the manufacturer, type of product, date, new product or renewal of registration, and all documents specified in "Register Control".
Defined Criteria	The criteria for refusal are: a) when the results of quantitative chemical analysis or others do not agree with those stated in the application for registration, and the difference is greater than the quantities accepted as a margin of error of the analytical technicians and the criteria of the Laboratory of the Ministry of Agriculture and Livestock; b) when, in utilization assays, it is seen that the product is not efficacious for the purposes stated in the respective application; c) when in the technical information it seems that the use of the product is highly dangerous for human health; and d) when the legal requisites are not present.
Foreign Studies Accepted	Yes.
Exempt Products	No.
Adverse Reactions Reported	Yes.
Post Registration Reporting	No.
Post Registration Surveillance	Yes.
Importation Requirements	Yes.
Manufacturing Inspection	Yes.

GRENADA

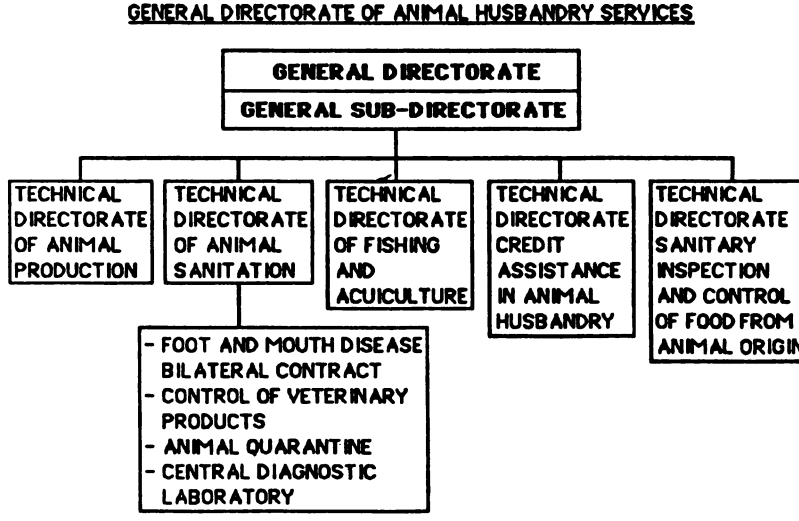
Legal Basis	People's Law Nº 97 of 1979. A law to incorporate the Pharmaceutical Association and to establish a Pharmacy Council to regulate the registration of pharmacists and for connected purposes. Printed by the government printer at the Government Printing Office, St. George's Grenada, W.I.
Registration Authority	The Pharmacy Council.
Human Resources	Physicians: 2 Pharmacists: 4 Member of the Chamber of Commerce: 1
Official Registration Document	--
Registration Procedures	--
Time for Registration Approval	--
Information Required for Registration	--
Defined Criteria	Yes.
Foreign Studies Accepted	Yes.
Exempt Products	No.
Adverse Reactions Reported	Yes.
Post Registration Reporting	Yes.

Post Registration Surveillance	Yes.
Importation Requirements	Yes.
Manufacturing Inspection	No.

Bases Legales	Regulations for the Control of Biological Products, Chemicals, Pharmaceuticals, Pesticides used in animals. Regulation of services that do not require a professional degree. 1981. Regulations for quality control, manufacturing, sale and distribution of food for animal use. 1980. Published by: Ministry of Agriculture, Livestock and Feedings, General Directorate of Animal Husbandry Services, Technical Directorate of Animal Health. Guatemala, C.A. They can also be obtained in the offices of the *Diario de Centro América*. 18 Calle 6-72, Zona 1, 3 nivel Edificio Tipografía Nacional, Guatemala.
Registration Authority	Ministry of Agriculture, Livestock and Feedings, General Directorate of Animal Husbandry Services, Technical Directorate of Animal Health, Department of Control of Veterinary Products
Human Resources	Veterinarians: 1 Assistants: 4
Official Registration Document	The details for the registration of veterinary products are specified in the Regulations for the Control of Biological Products, Chemicals, Pharmaceuticals, Pesticides used in animals and Regulation of services that do not require a professional degree ("Reglamento para el Control de Productos Biológicos, Químicos Farmacéuticos, Pesticidas para uso en animales y Servicios para los cuales no se require título profesional").
Registration Procedures	The manufacturing company mus be registered in the Department of Control of Veterinary Products in order to get the necessary licence. There is a special form

	for the registration of veterinary products that must be presented with three copies to the Department of Control. The application must also include samples of the product, proposal of labels, brochures and propaganda literature, and the certificates specified in the Regulations.
Time for Registration Approval	The Department of Control must notify whithin 30 days if the application is complete or if additional information is required to resolve about the approval for registration. The licence is valid for 3 years from the authorization date.
Information Required for Registration	Trade and scientific name of the product; form of presentation; pharmacological classification; global formula and chemical composition; name, address and telephone number of the person registering the product; manufacturing company; place of origin; distributor with its address and phone number; name and registration number of the Veterinarian responsible for the application; expiration date of the product and possible modifications that may occur with time; storage conditions; free sale certificate from the country of origin; method of qualitative and quantitative analysis recommended by the manufacturer.
Defined Criteria	Yes. Registration is refused when products are harmful for human or animal health and/or imported from countries under quarantine.
Foreign Studies Accepted	In some instances yes, when local laboratory tests can not be performed.
Exempt Products	Only raw materials.
Adverse Reactions Reported	Yes. Sections 48-59-66.
Post Registration Reporting	Yes. Sections 47-48-78-79.

Post Registration Surveillance	Yes. Section 114.
Importation Requirements	Yes. Sections 45-81-82-83-84.
Manufacturing Inspection	Yes. Sections 109-110-111-112-114-118.



GUYANA

Legal Basis

Regulation Nº 10 of 1977. Regulations under the Food and Drugs Act, Chapter 34:03.

Published by the Attorney General's Chambers, Government of Guyana. 95, Carmichael Street, Georgetown, Guyana.

They can be obtained from the Government Analyst - Food and Drug Department. 19-21, Lyng and Evans Streets, Charlestown, Georgetown, Guyana.

Registration Authority

a) Guyana National Medical Formulary Committee (GNMFC). Government Analyst/Food and Drug Department, Ministry of Health.
b) Veterinary Services and Guyana Stockfeeds Limited (GSF Ltd.), Guyana Pharmaceutical Corporation (GPC).
c) Licensing Division, Ministry of Trade and Consumer Protection.
d) Customs and Excise Department, Ministry of Finance.

Human Resources

Veterinarians:	2
Physicians:	10-20
Pharmacists:	2
Chemists:	3
Analysts:	2

Official Registration Document

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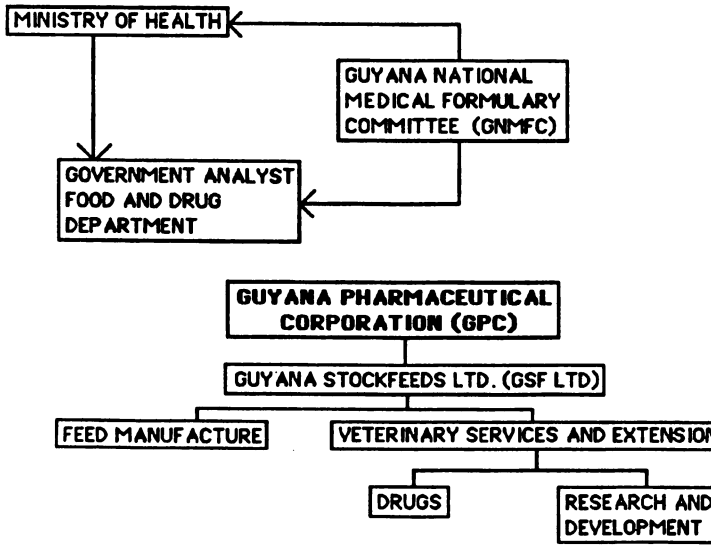
Registration Procedures

There is a standard application for new drugs made by the Guyana Pharmaceutical Corporation, the only importer of new drugs to the country. Every product must be included in the application with its generic name.
Licences may be given to private importers recommended by CFG only if:
a) the drugs are registered;

	b) there will not be money exchange; c) there is no provider in the country.
Time for Registration Approval	--
Information Required for Registration	--
Defined Criteria	Yes. Criteria for refusing are: a) insufficient supporting documents, trials, samples, etc; b) insufficient evidence of efficacy; c) alternate drugs available in the country; d) adverse reactions or susceptibility to drug abuse; e) evidence that the drug is not marketable in the country of manufacture; f) drugs banned in other countries being utilized for commercial purposes.
Foreign Studies Accepted	Yes.
Exempt Products	No. Laws and regulations apply for all drugs, human or otherwise. Regulations apply to new drugs, having not been imported into Guyana before January 1, 1977 or if combinations of drugs used subsequently varied, or if new claims of usage.
Adverse Reactions Reported	Yes. Stated in the Regulations.
Post Registration Reporting	Yes.
Post Registration Surveillance	No.
Importation Requirements	Yes.
Manufacturing Inspection	Yes. It is responsibility of the Analyst/Food and Drug Department.

GUYANA


MINISTRY OF HEALTH
GUYANA NATIONAL MEDICAL FORMULARY COMMITTEE (GNMFC)
GOVERNMENT ANALYST FOOD AND DRUG DEPARTMENT
GUYANA PHARMACEUTICAL CORPORATION (GPC)
GUYANA STOCKFEEDS LTD. (GSF LTD)
FEED MANUFACTURE
VETERINARY SERVICES AND EXTENSION
DRUGS
RESEARCH AND DEVELOPMENT

Legal Basis	Laws are being developed.
Registration Authority	None. Approval for products to enter the country must be obtained from Customs.
Human Resources	See "Registration Authority".
Official Registration Document	--
Registration Procedures	--
Time for Registration Approval	--
Information Required for Registration	--
Defined Criteria	No.
Foreign Studies Accepted	--
Exempt Products	Not applicable.
Adverse Reactions Reported	Not applicable.
Post Registration Reporting	Not applicable.
Post Registration Surveillance	--
Importation Requirements	--
Manufacturing Inspection	--

HONDURAS

Legal Basis

Regulations for the Control of Plaguecides, Pharmaceutical and Biological Products for Veterinary Use.
Published in the Official Newspaper *La Gaceta*. Agreement Nº 325, 3 November, 1980. They can be requested in the Rent Administration Office at each Department (Department is each geographic area of the country).

Registration Authority

Service for Control of Veterinary Drugs, Department of Regulations and Control of Animal Husbandry, General Directorate of Livestock,Secretariat of Natural Resources.

Human Resources

Veterinarian:	1
Attorney at Law:	1
Secretary:	1
Administrative Personnel:	1
Other:	1

Official Registration Document

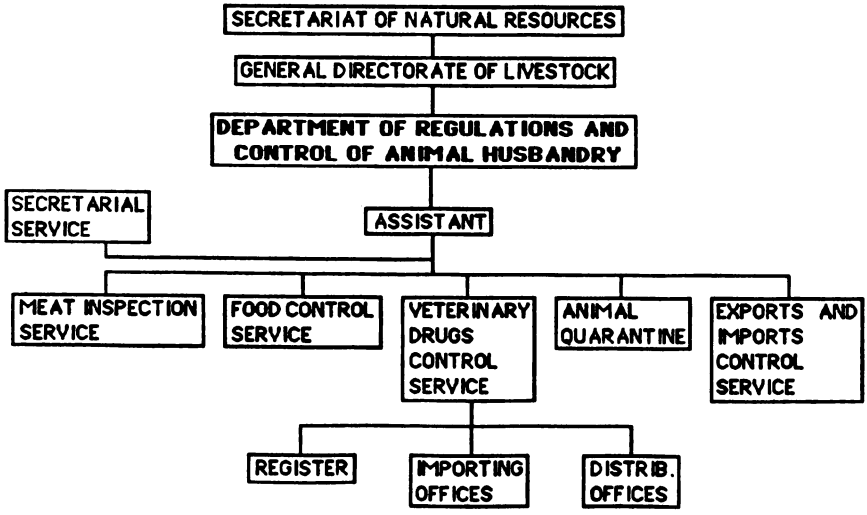
Regulations for the Control of Plaguecides, Pharmaceutical and Biological Products for Veterinary Use ("Reglamento para el Control de Plaguicidas, Productos Farmacéuticos y Biológicos de Uso Veterinario") contains all the information related to registration of veterinary products.

Registration Procedures

The application for registration must be presented by a Veterinarian at the Service for Control of Veterinary Drugs of the Secretariat of Natural Resources.The following documents need to be enclosed: a free sale certificate from the country of origin legalized by the consulat authorities of Honduras in the case of imported products; authorization of the manufacturer so the applicant can commercialize the product; four samples of the product; copy of the labels.

	The registration fee is US$12.50 for each product. The legal fees are not standard, but they are normally under US$50.00 for each product. The importers of national manufacturers must be registered at the Service for Control of Veterinary Drugs of the Secretariat of Natural Resources before registering their products. This licence is valid for 5 years.
Time for Registration Approval	If the registration of a product is refused, the Secretariat of Natural Resources, through the respective office, will notify the applicant in a period no greater than 8 days. The applicant may ask for a review of the application based on new technical evidence presented with the claim. The licence is valid for 3 years.
Information Required for Registration	Trade name, qualitative and quantitative formulas, free sale certificate from the country of origin, authorization of the manufacturer to commercialize the product, methods of analysis, description of the raw materials and samples for the respective analysis, indications, contraindications, name of the institution that will distribute the product, pharmacological information and scientific publications supporting the benefits of the product, period of effectiveness.
Defined Criteria	Yes. Refusal of registration occurs when, for technical and security reasons, it is found that the product is harmful for animals, people who manage it or consumers of food animals to which the product have been administered, or its use is against the national economy.
Foreign Studies Accepted	Yes.
Exempt Products	No.

Adverse Reactions Reported	Only if the specifications indicate the possibility of any adverse reaction.
Post Registration Reporting	Not enforced by law.
Post Registration Surveillance	The law requires surveillance by the authorities of the utilization of veterinary products.
Importation Requirements	Yes.
Manufacturing Inspection	Yes. The Service is required by law to inspect these industries



Legal Basis	Drugs and Poisons Law. Published in the Jamaica Gazette, Government Printing Office. Laws may be obtained from the Ministry of Health and Environmental Control.
Registration Authority	Pharmaceutical Services Division, Ministry of Health and Environmental Control.
Human Resources	None.
Official Registration Document	Drugs and Poisons Law.
Registration Procedures	The application for registration must be presented to the Pharmaceutical Services Division with: five samples of the product in the form that it will be sold to the public and five copies of the proposed labels. The following documents must also be enclosed: a certificate from the country of origin stating that the product is approved for use in that country, and a certificate of the manufacturer assuring the safety of the product, recommended conditions for its use and selling conditions.
Time for Registration Approval	--
Information Required for Registration	Trade name;generic name;name and address of the manufacturer; name and address of the person presenting the application; three copies of the following information: ingredients, administration route, dosage, purpose for its use, form of expenditure, contraindications or adverse effects; details about tests of potency, purity and security; summary of the manufacturing techniques; certificate of analysis containing: information of tests performed on a recently manufactured product, methods of analysis

	utilized and specification of the raw materials used; countries in which the product is sold besides the country of origin; countries in which the drug has been banned for its use.
Defined Criteria	Yes.
Foreign Studies Accepted	Yes.
Exempt Products	No.
Adverse Reactions Reported	Yes.
Post Registration Reporting	Yes
Post Registration Surveillance	Yes.
Importation Requirements	Yes.
Manufacturing Inspection	Yes.

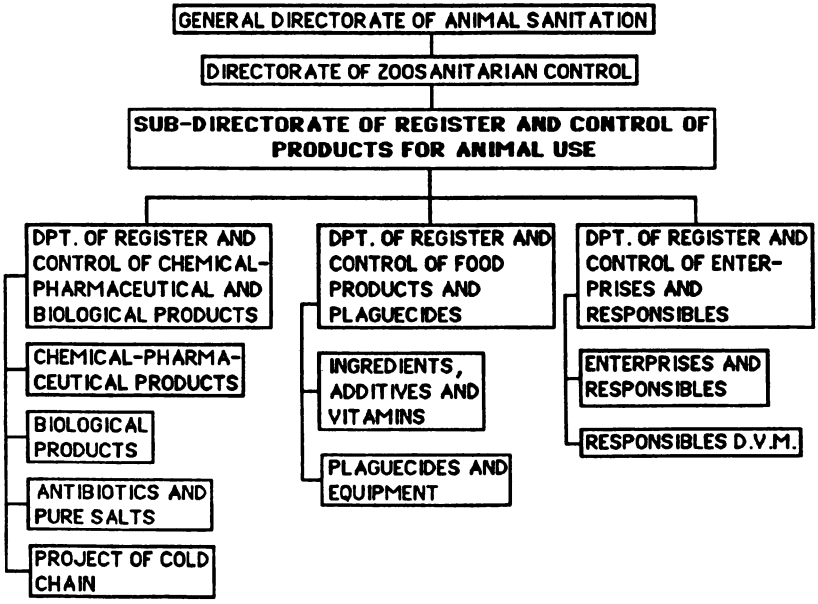
MEXICO

Legal Basis	Federal Law of Sanitation of Plant and Animal Husbandry, and its Regulation for the Control of Chemical-Pharmaceutical, Biological and Food Products, Equipments and Services for Animals. Published in the Official Newspaper of December 13, 1974. Regulations were published in the Official Newspaper of January 12, 1979. Both can be obtained from the General Directorate of Animal Sanitation, Doctor Mora Nº 15. 9º Piso. Centro C.P. 06050 Mexico, D.F.
Registration Authority	Sub Directorate of Register and Control of Products for Animal Use, a unit of the General Directorate of Animal Sanitation, Secretariat of Agriculture and Hydraulic Resources.
Human Resources	Veterinarians: 10 Licentiate in Nutrition and Foods: 1 Licentiate in International Relations: 1 Licentiate in Biology: 1 Pharmacists: 2 Chemists,Bacteriologists,Parasitologists: 2
Official Registration Document	Details about the registration of veterinary products are specified in the Regulation for the Control of Chemical-Pharmaceutical, Biological and Food Products, Equipments and Services for Animals ("Reglamento para el Control de Productos Químico-Farmacéuticos, Biológicos, Alimenticios, Equipo y Servicios para Animales") It may be obtained from: Dirección General de Sanidad Animal. Dr.Mora, Nº 15. 9º Piso. Centro C.P. 06050, Mexico, D.F.
Registration Procedures	The company must have a valid zoosanitarian licence to be able to apply for the registration of raw materials, ingredients or veterinary products. There is an official application form that can be obtained from

	the Secretariat of Agriculture and Hydraulic Resources paying the required fee. The application must be presented with: proposed labels, containers, brochures or propaganda literature, samples of the product, manufacturing techniques and quality control. If the case of imported producs: a document authorizing the manufacture of the product by the company.
Time for Registration Approval	A temporary resolution will be given in 15 days after the application was presented. The final licence will be given once the laboratory tests have been informed. If complementary information is required, the Secretariat will set a new date for the licence to be decided. The permit to manufacture the product is valid for two years, and the registration of the product one year from the date of the final notification.
Information Required for Registration	Trade name,generic name,formula, dosage, precautions for its use, complementary information specified in the Regulation. If the product has an active ingredient not present in the national or international pharmacopoeias, the original papers published in journals with their translations to Spanish must be included. The Secretariat may accept the results of research done for other companies or researchers under the supervision of personnel assigned by the Secretariat.
Defined Criteria	Yes. Refusal occurs when products do not meet the requirements of the Federal Law of Sanitation of Plant and Animal Husbandry and its Regulations, in its chapters I, IV. Also, in the case of products that do not include a therapeutic advance, that are not registered in their original country in the case of imported products, or that the strain of biologicals or active principles are against the policy of the General Directorate of Animal Sanitation in

	relation to zoosanitarian campaigns that are a priority for the country.
Foreign Studies Accepted	Yes. They must meet conditions and regulations indicated in the Federal Law. Tests and analysis must be performed in Mexico and a copy of the Register of the original country must be presented.
Exempt Products	Yes. Food for ornamental birds that is not a mixture. An example is seeds.
Adverse Reactions Reported	Yes.
Post Registration Reporting	Yes. The results of field tests performed by industries and laboratories to their products, once registered, are used to request changes in concentrations, physical presentation, ways of use, indications.
Post Registration Surveillance	Yes, by the personnel in charge of the inspection and surveillance in the States and the Federal District.
Importation Requirements	Yes. They are specified in the Federal Law, Chapter V.
Manufacturing Inspection	Yes. Inspections are performed by personnel belonging to the Sub-Program of Animal Sanitation in all the States o the Republic.

MEXICO


GENERAL DIRECTORATE OF ANIMAL SANITATION
DIRECTORATE OF ZOOSANITARIAN CONTROL
SUB-DIRECTORATE OF REGISTER AND CONTROL OF PRODUCTS FOR ANIMAL USE
DPT. OF REGISTER AND CONTROL OF CHEMICAL-PHARMACEUTICAL AND BIOLOGICAL PRODUCTS
CHEMICAL-PHARMACEUTICAL PRODUCTS
BIOLOGICAL PRODUCTS
ANTIBIOTICS AND PURE SALTS
PROJECT OF COLD CHAIN
DPT. OF REGISTER AND CONTROL OF FOOD PRODUCTS AND PLAGUECIDES
INGREDIENTS, ADDITIVES AND VITAMINS
PLAGUECIDES AND EQUIPMENT
DPT. OF REGISTER AND CONTROL OF ENTERPRISES AND RESPONSIBLES
ENTERPRISES AND RESPONSIBLES
RESPONSIBLES D.V.M.

NICARAGUA

Legal Basis	Legislative Decree Nº 568: "Law of Registration of Medicines, Cosmetics, etc." of March 11, 1961. Legislative Decree Nº 17: "Regulation of the Law of Registration of Medicines, Cosmetics, etc." of February 27, 1962. Published in the Official Newspaper *La Gaceta.* The decrees may be obtained in the Ministry of Agriculture and Livestock. Managua, D.N., Nicaragua.
Registration Authority	Section Registration and Animal Husbandry Control, Animal Sanitation, Ministry of Animal Husbandry Development and Agrarian Reform (MIDINRA).
Human Resources	--
Official Registration Document	The registration procedures are specified in the Regulation of the Law of Registration of Medicines, Cosmetics, etc.("Reglamento de la Ley de Registro de Medicinas, Cosméticos, etc."). It may be requested from: Ministerio de Agricultura y Ganadería, Managua D.N., Nicaragua. There is an official application form that must be presented to the respective office.
Registration Procedures	The application must be accompanied by: 6 samples of the product, free sale certificate legalized by the Nicaraguan Consulate of the country of origin, certificate of registration of Trade Name of the Ministry of Justice of Nicaragua (Register of Trade Names and Patents). The products with specific names must pay a registration fee of C$600.00. These same products must pay C$500.00 for the renewal of the licence. The products manufactured in the country which companies are under the Law of

	Protection and Enhancement of Industrial Development or any other law related to them are exempt of payment.
Time for Registration Approval	Every product will be assigned with a control number. This number will be informed to the General Directorate of Revenues at the most 5 days after the payment of the fee. The registration licence will not be valid after December 31 of the year in which it was extended, whenever the date of the registration. The registration renewals must be presented within the first three months of the year.
Information Required for Registration	Name of the person applying for the registration; imported or national product; distributor of the product; complete address; name of the company and country of origin; name of the product; presentation; qualitative and quantitative formulas; therapeutic properties; dosage; literature in Spanish; certificates mentioned in "Registration Procedures".
Defined Criteria	Yes.
Foreign Studies Accepted	Yes.
Exempt Products	--
Adverse Reactions Reported	--
Post Registration Reporting	--
Post Registration Surveillance	--
Importation Requirements	Yes.
Manufacturing Inspection	--

PANAMA

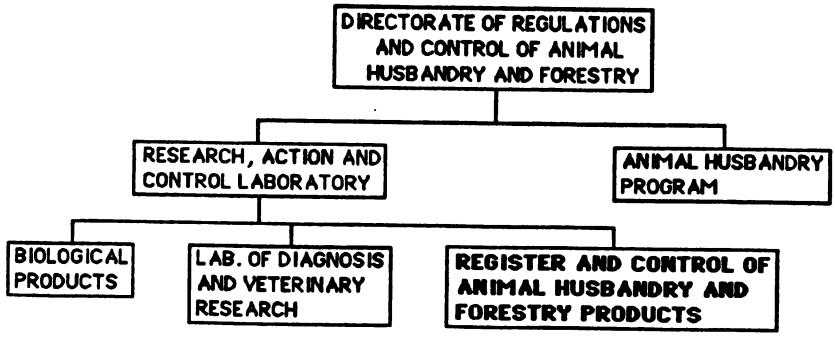
Legal Basis	Decree Nº 93, February 16, 1962. Sanitary Code and Law 31 of April 7, 1941.
Registration Authority	Department of Pharmacy and Drugs, Ministry of Health.
Human Resources	Pharmacists: 7
Official Registration Document	There is a booklet printed by the Department of Pharmacy and Drugs, Ministry of Health which describes all the registration procedures.
Registration Procedures	The application must be presented in stamped paper, through a lawyer, to the Department of Pharmacy and Drugs. This application must also be legalized by the National Association of Pharmacists, and accompanied by: a certificate given by the company, naming a legal representative to register and distribute the products. This certificate must be legalized by the Consulate of Panama in the original country and by the Minisry of Foreign Relations of Panama. The following documents must also be enclosed with the application: a free sale certificate legalized by the Consulate of Panama in the country of origin which will state the manufacturing company and the name of the product; four labels or proposed labels; four original samples belinging to the same batch; brochures and propaganda literature; approval for use extended by the Institute of Animal Husbandry Research and the Department of Plant Sanitation. The registration renewals must be presented at leat 6 months before the expiration date.
Time for Registration Approval	--

Information Required for Registration	Two copies of the qualitative and quantitative formulas of the product with the generic names of the ingredients; if colorants are used, international code number; if plastic containers are used, type of material and stability of the product in relation to those containers; two copies of the method of analysis used for the manufacturing company to check purity and therapeutic activity of the product or reference to the official methods used for this purpose; batch number; storage temperature; expiration date; manufacturing laboratory and country; pharmacological and clinical studies for those products not described in the pharmacopoeia; certificates named in "Registration Procedures".
Defined Criteria	Yes. Refusal occurs when the products do not meet the requirements described in the document "Basic Requirements for Sanitarian Registration". There are also defined criteria on the import of biological products from countries with foot and mouth disease.
Foreign Studies Accepted	Only from internationally recognized organizations.
Exempt Products	No.
Adverse Reactions Reported	Yes.
Post Registration Reporting	Yes.
Post Registration Surveillance	Yes.
Importation Requirements	Agreement with Decree Nº 93.Registration, import and management.
Manufacturing Inspection	Yes.

PARAGUAY

Legal Basis	Law Nº 462, October 17, 1974. Law Nº 494, May 13, 1921. Law Nº 675, December 20, 1977 and Regulations. Decree Nº 19,268, June 17, 1966. Decree Nº 28,675, October 2, 1977. Published by: - Legislative and Executive Powers. - Directorate of Regulations and Control of Animal Husbandry. - SENACSA.
Registration Authority	Directorate of Regulations and Control of Animal Husbandry and Forestry. National Service of Animal Sanitation (SENACSA).
Human Resources	Veterinarians: 2 Biochemists: 1 Assistants: 2
Official Registration Document	--
Registration Procedures	--
Time for Registration Approval	--
Information Required for Registration	--
Defined Criteria	Yes: fraud, alterations, lack of efficiency.
Foreign Studies Accepted	Yes.
Exempt Products	Yes (partially). Those products which have entered in irregular way to the country and that are difficult to register.

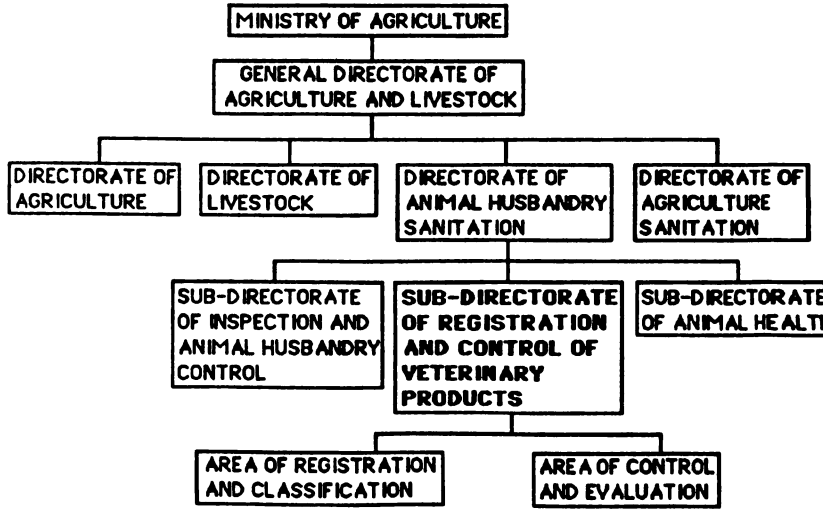
Adverse Reactions Reported	Yes.
Post Registration Reporting	No.
Post Registration Surveillance	Yes
Importation Requirements	Yes. In addition to the laws listed above, there is a law about labeling, Municipality of Asuncion. 1964.
Manufacturing Inspection	Yes.



Legal Basis	Regulation of Registration and Control of Veterinary Products. Approved by Supreme Decree Nº 124-81-AG, published in August 6, 1981. Published in August 11, 1981 issue of the Official Newspaper *El Peruano* and also by the Inter-American Institute for Cooperation in Agriculture, Peru Bureau in the "Compendium of Regulations for Animal Health in Peru" (Miscellaneous Publication Nº 449-ISSN-0534-5391).
Registration Authority	Sub-Directorate of Registration and Control of Veterinary Products, Directorate of Animal Husbandry Sanitation, General Directorate of Agriculture and Livestock, Ministry of Agriculture.
Human Resources	Veterinarians: 3
Official Registration Document	The registration process is described in the document: Regulation of Registration and Control of Veterinary Products ("Reglamento de Registro y Control de Productos Veterinarios"). The document: Model of Application for Registration (Renewal) of National or Foreign Veterinary Products ("Modelo de Solicitud de Inscripción (Reinscripción) de Productos Veterinarios Nacionales y Extranjeros") must be filled out by the applicant.
Registration Procedures	The application must be presented to the General Director of Agriculture and Livestock, Ministry of Agriculture. The registration must be accompanied by the receipt of the registration fee (or renewal fee) paid in the Administration Office of the General Directorate of Agriculture and Livestock, and it is equivalent to 20% of the minimum salary for the Metropolitan Lima. In the case of imported products, a

	free sale certificate extended by the sanitary authority of the country and legalized by the Peruvian Consulate and the Ministry of Foreign Relations must also be presented.
Time for Registration Approval	--
Information Required for Registration	Trade name; origin (national or foreign); manufacturing company; qualitative and quantitative formulas; presentation; pharmacological information of the active ingredients and copy of the papers demonstrating the efficacy of the product for the indicated purposes; three copies of labels and brochures in spanish; technical regulations for the quality control of the product. The following points must appear in the labels and/or propaganda literature: trade name of the product; the words "For Veterinary Use"; qualitative and quantitative formulas with their centesimal composition; name of the manufacturing company; indications; contraindications; recommended dosage; serie or batch number; name of the responsible professional (only for national products); expiration date; registration number given by the Ministry of Agriculture; storage conditions; the word "POISON" in the case of toxic products with the corresponsing symbol and handling conditions; antidotes and first aid in case of accident.
Defined Criteria	Refusal occurs when reports from national or foreign organizations indicate that the product may be harmful for animals or humans (public health). Registration is also refused for vaccines against diseases not present in the country, or coming from countries affected by exotic diseases.
Foreign Studies Accepted	Yes. Those performed by foreign scientific institutions.
Exempt Products	No.

Adverse Reactions Reported	The regulations require that the labels and instructions for the user indicate the adverse reactions that can occur, and also it is required to name the antidotes or precautions that are necessary to prevent adverse effects.
Post Registration Reporting	No. If any adverse effect is observed and it was not reported by the manufacturer, the granted registration for the product can be cancelled.
Post Registration Surveillance	Yes. Regulations require that products must be stored properly according to instructions. Periodic inspections to the stores are performed to determine that the instructions are being followed and selling of expired products is prevented.
Importation Requirements	To import veterinary products, the importing company and the product must be previously registered.
Manufacturing Inspection	Yes. The inspection is performed by the regional veterinarian in charge of this duty and animal husbandry control under, the supervision of the national central service.



ST. LUCIA

Legal Basis	None.
Registration Authority	None.
Human Resources	None.
Official Registration Document	--
Registration Procedures	--
Time for Registration Approval	--
Information Required for Registration	--
Defined Criteria	No.
Foreign Studies Accepted	No.
Exempt Products	No.
Adverse Reactions Reported	No.
Post Registration Reporting	No.
Post Registration Surveillance	No.
Importation Requirements	No.
Manufacturing Inspection	No.

Legal Basis	None.
Registration Authority	None.
Human Resources	None.
Official Registration Document	--
Registration Procedures	--
Time for Registration Approval	--
Information Required for Registration	--
Defined Criteria	No.
Foreign Studies Accepted	Not applicable.
Exempt Products	Not applicable.
Adverse Reactions Reported	Not applicable.
Post Registration Reporting	No.
Post Registration Surveillance	No.
Importation Requirements	Yes.
Manufacturing Inspection	No.

UNITED STATES

Legal Basis

Drug products and feed additives registration: Federal Food, Drug and Cosmetic Act (1938, as amended in 1962).

Biologicals registration: Virus, Serum, and Toxins Act (1931).

Pesticide products registration: Federal Insecticide, Fungicide and Rodenticide Act (1947 as amended in 1972 and 1975).

Each agency has also established regulations which are revised as needed under these laws.

U.S. laws and regulations may be obtained at nominal cost from the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402.

Registration Authority

Animal and Plant Inspection Service, U.S. Department of Agriculture (APHIS); Environmental Protection Agency (EPA); Food and Drug Administration, Department of Health and Human Services (FDA).
Biologicals are registered by APHIS; pesticides products are registered by EPA; drugs, including drug products used in feeds, and non-drug additives for use in feeds are approved by FDA.
Agreements between agencies define which agency will regulate products subject to more than one law.

Human Resources

FDA:
Veterinarians: 34
Chemists: 21
Others: 29 (animal scientists, statisticians, pharmacologists, microbiologists, environmental officers, consumer safety officers, parasitologists).

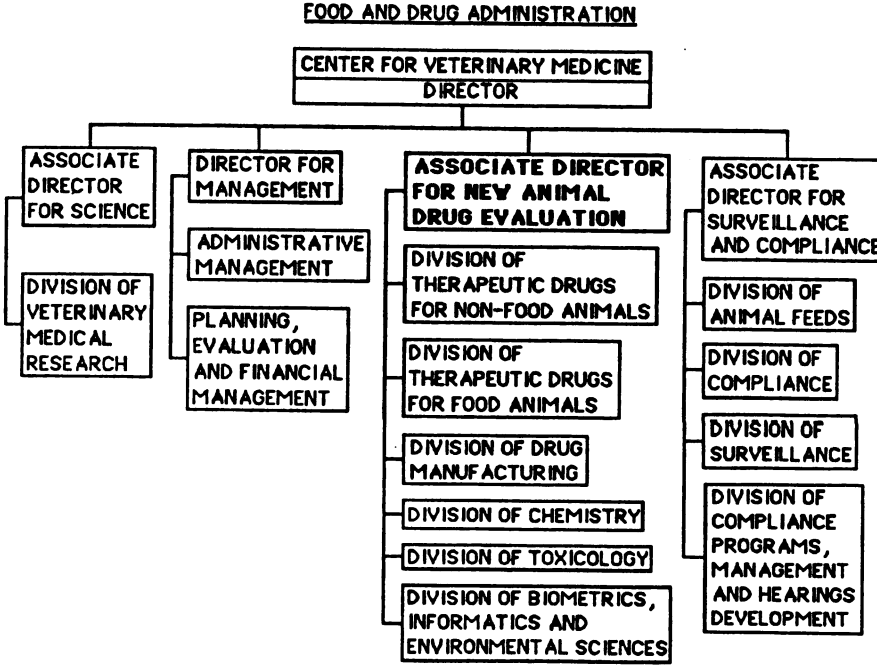
Official Registration Document

A special registration form must be filled out in order to register a veterinary product. There is no registration fee. The form may

	be obtained from: Center for Veterinary Medicine, Food and Drug Administration. 5600 Fishers Lane. Rockville, MD 20857.
Registration Procedures	The registration form must be addressed to: Center for Veterinary Medicine, Food and Drug Administration.
Time for Registration Approval	The law requires notification within 180 days of filing for registration.
Information Required for Registration	Detailed information on manufacturing, efficacy, target animal safety, human food safety and environmental impact is required. Details can be obtained by writing to the Center for Veterinary Medicine.
Defined Criteria	Yes. U.S. agencies have defined criteria for refusal of veterinary products registration.
Foreign Studies Accepted	Yes. Foreign data can be used to support drug product registration provided the data meet the same quality requirements as domestic data. In most cases foreign data may not serve as the total data requirements.
Exempt Products	The law provides for registration exemption for drug products but no exempting criteria have been established and the exempting provision has not been implemented.
Adverse Reactions Reported	Yes.
Post Registration Reporting	Yes.
Post Registration Surveillance	Yes. U.S.laws provide authority to inspect, analyze, and conduct other surveillance of registered products.
Importation Requirements	Yes. Products imported into the U.S. are subject to the same requirements as domestic products.

Manufacturing Inspection

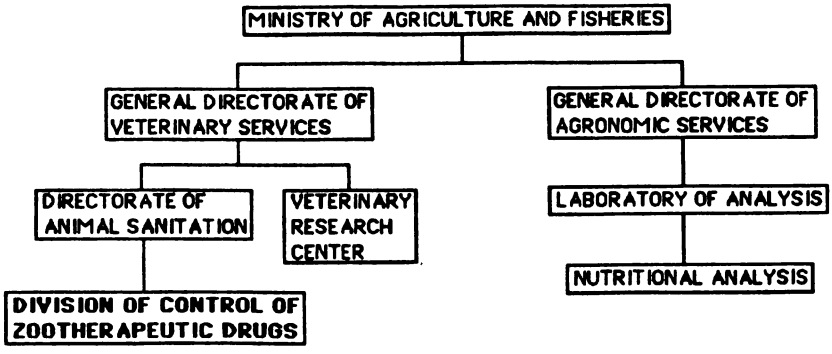
Yes. U.S. agencies do inspect pharmaceutical manufacturing establishments.



URUGUAY

Legal Basis	Law Nº 3606 of April 13, 1910: Sanitary Police for Animals. Decree of March 20, 1936: Regulations about Control of Zootherapeutic Drugs. Besides these, there are actual resolutions according to the scientific development in the field of product control, and they are adjusted to Law 3606 and Decree mentioned above. Published as a Compendium in 1979. They can be obtained from the Directorate of Animal Sanitation.
Registration Authority	The registration of drugs and biologicals is done by the Ministry of Agriculture and Fisheries, General Directorate of Veterinary Services. They perform control by two ways: - by the Directorate of Animal Sanitation, Division Inspector of Drugs; - by the Veterinary Research Center "Miguel C. Rubino" (CIVET). The General Directorate of Agronomic Services also works in this matter performing control through its Laboratory of Analysis. The registration of feed additives is done by the General Directorate of Agronomic Services.
Human Resources	Division of Zootherapeutic Drugs (CIVET):1 Laboratory of Analysis: 4
Official Registration Document	--
Registration Procedures	--
Time for Registration Approval	--

Information Required for Registration	--
Defined Criteria	Yes. The criteria for refusal are: a) lack of efficaciousness; b) unsafety for the animals; c) inconvenience for its use in national livestock.
Foreign Studies Accepted	The application must be submitted with the scientific information assuring the efficacy and safety of the product.
Exempt Products	No.
Adverse Reactions Reported	No.
Post Registration Reporting	No.
Post Registration Surveillance	Yes.
Importation Requirements	Yes.
Manufacturing Inspection	Yes.



VENEZUELA

Legal Basis

Decree 911 of May, 1975: Law of fertilizers and other susceptible agents that might perform an action.

Decree 43 of August 1, 1952: Slaughtering in animals, plants, soils and water.

Law about plant and animal sanitary defense (1941).

Published in the Official Newspaper of the Republic of Venezuela, *Gacetas Oficiales*.

Registration Authority

Department of Product's Control for Animal Use (DCPPUA). It is in charge of everything related to manufacture, import, export, warehousing and distribution of drugs, pesticides, vitamins, minerals, food and biologicals.

Human Resources

	DCPPUA
Veterinarian:	1
Pharmacist:	1
Microbiologist:	1
Biologist:	1
Chemical Technician:	1

Official Registration Document

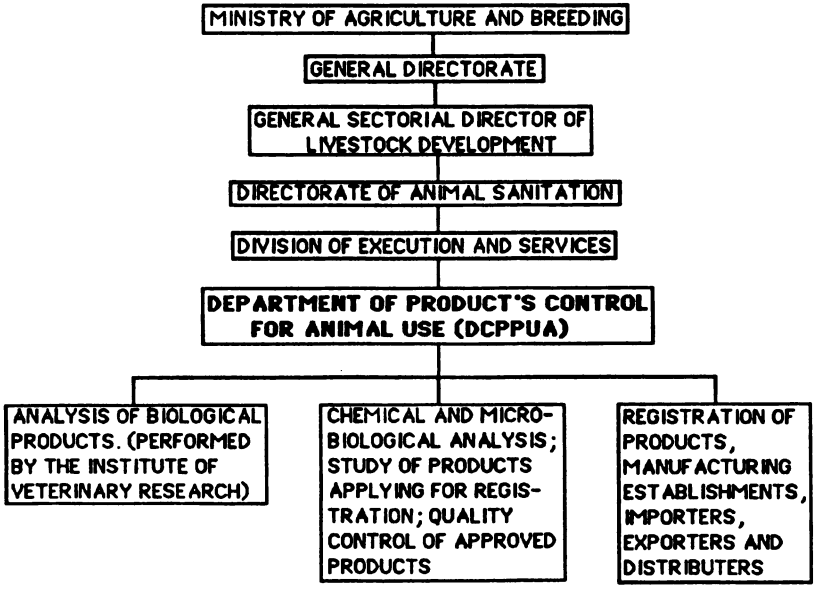
The information is available in Decree 911published in the *Gaceta Oficial* Nº 30.740. Besides, the following documents are available:

- Communication Model Applying for the Registration of Enterprises whose Activities are Regulated by Decree 911 ("Modelo de Comunicación Solicitando el Registro de Empresas cuyas Actividades están Reguladas por el Decreto 911").
- Model of Application for Authorization of Manufacture or Import of Products for Animal Use ("Modelo de Solicitud de Autorización para Fabricar o Importar Productos para Uso Animal").

Registration Procedures	The company wanting to manufacture, sell or distribute products for animal use must register, submitting the aplication to the General Sectorial Director of Livestock Development, of the Ministry of Agriculture and Breeding, according to Art.2 of Decree 911. The application to manufacture or import products must be addressed to the Department of Product's Control for Animal Use, General Sectorial Directorate of Livestock Development, Ministry of Agriculture and Breeding. The application must be submitted with: samples of the product, label proposals, free sale certificate of the country of origin legalized by the consular authorities of Venezuela, letter of the manufacturing company authorizing the manufacture of the product (legalized by the Consulate of Venezuela).
Time for Registration Approval	--
Information Required for Registration	Name of the product; qualitative and quantitative formulas; description of the active ingredients indicating: formula, generic name, action, physico-chemical characteristics, pharmacological characteristics. In the case of new drugs: formula, physico-chemical constants, potency, purity, toxicity studies, lethal dose. In the case of association of several drugs: information justifying that the ingredients are compatible, recommendations for its use and routes of administration. The following information must also be included: contraindications, precautions for use and handling, description of toxic reactions, presentation, characteristics of the container, pharmaceutical form of the product, qualitative and quantitative methods of analysis of the raw materials and the final product. The application with the information described above must be presented by the veterinarian or pharmacist representing the company and must include the name of the

	professional, address and registration number of the representing company, name and address of the company manufacturing the product.
Defined Criteria	Yes. The criteria for refusal are: a) lack of free sale certificate in the case of imported products; b) knowledge of product toxicity (carcinogenic, teratogenic); c) products with active ingredients already available in the country.
Foreign Studies Accepted	Yes, but local research is requested in the case of new drugs.
Exempt Products	No.
Adverse Reactions Reported	No. They must be declared when the application is presented.
Post Registration Reporting	No.
Post Registration Surveillance	Yes.
Importation Requirements	No, but there are administrative regulations such as the presentation of a free sale certificate of the country of origin, legalized by the consular authorities of Venezuela.
Manufacturing Inspection	Yes.

VENEZUELA


MINISTRY OF AGRICULTURE AND BREEDING
GENERAL DIRECTORATE
GENERAL SECTORIAL DIRECTOR OF LIVESTOCK DEVELOPMENT
DIRECTORATE OF ANIMAL SANITATION
DIVISION OF EXECUTION AND SERVICES
DEPARTMENT OF PRODUCT'S CONTROL FOR ANIMAL USE (DCPPUA)
ANALYSIS OF BIOLOGICAL PRODUCTS. (PERFORMED BY THE INSTITUTE OF VETERINARY RESEARCH)
CHEMICAL AND MICRO-BIOLOGICAL ANALYSIS; STUDY OF PRODUCTS APPLYING FOR REGISTRATION; QUALITY CONTROL OF APPROVED PRODUCTS
REGISTRATION OF PRODUCTS, MANUFACTURING ESTABLISHMENTS, IMPORTERS, EXPORTERS AND DISTRIBUTERS

FECHA DE DEVOLUCION